DEPARTMENT OF HEALTH AND HUMAN SERVICES

TELECONFERENCE MEMORANDUM

Public Health Service
Food and Drug Administration
Center for Biologics Evaluation and Research

Date\Time: January 31, 2007 \ 11am-12 pm

CBER Representatives: Ke Liu, Boguang Zhen, Peter Bross, Ashok Batra

Sponsor's Representative: Elizabeth Smith

STN : 125197/0

Subject: Revised progression dates

Questions to Dendreon:

1. ***Could you provide the details on the information related to the attachment 1? Specifically, the information on the revised progression dates for the subjects contained in the attachment 1.***

2. ***We would like to discuss with you regarding the text in the proposed label, sentence number 104 "Overall survival at 36 months was a pre-specified analysis." Please provide detailed information to support this statement.***

Dendreon Response:

The sponsor pointed out that analysis on overall survival at 36 months was mentioned in Section "9.6.2.1 Primary endpoint".

The CBER statistician questioned on the 'survival rate" statement in this section. It is very unclear whether the so-called "survival rate" and "median survival" just refer to the survival analysis methods for analyzing the primary endpoint or have something to do with a survival endpoint. If this is for a survival endpoint, what did the survival endpoint the sponsor intend to use since no survival endpoint was defined in the protocol? (it could be an overall survival or a cause-specific survival or a treatment-relative survival endpoint with different starting time point and censoring status)

The sponsor agreed they did not define a survival endpoint for the analysis, but said it should be the overall survival by “common sense”.

The CBER statistician pointed out and the sponsor agreed that there was no pre-specified plan for any hypothesis test for an effect for overall survival or any other survival endpoints. This means that the sponsor did not pre-specify a statistical analysis method for the primary comparison between the two arms in overall survival—the comparison resulted in key efficacy evidence in support of the licensing application.

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